

**REMARKS**

Applicant would like to thank the Examiner for the careful consideration given the present application. The application has been carefully reviewed in light of the Office action, and amended as necessary to more clearly and particularly describe the subject matter which applicant regards as the invention.

Claims 1, 3, 5, and 16 are presented for examination. Of these claims, claims 1 and 5 have been allowed and will not be discussed at length hereinafter.

Claim 1 has been amended to correct a potential minor formal error discovered during preparation of the present amendment. It is not believed that this amendment to claim 1 affects the scope of the claim, but rather clarifies the claim. However, with regard to the Examiner's reasons for allowance of claim 1, some further clarification is considered appropriate. The Examiner has stated that the prior art does not teach or suggest "a needle having an outer surface coated with a coating material that includes a noble metal including platinum, a platinum group metal, or gold and an interior surface coated with the same outer coating in addition to a thin film of quartz and a needle containing a non-noble base metal that includes nickel or chromium". However, this is not what is defined in claims 1 and 5.

Rather, claim 1 clearly states that the outer surface of the needle is coated with a first coating material, while the inner surface of the needle is coated with a second material. Nowhere in claim 1 is it required that the inner surface of the needle be coated with both the first and second materials. Further, claim 5 clearly states that the needle is formed from a non-noble base metal and has an outer surface coated with a coating material that has a chemical activity lower than a

chemical activity of iron and is plated or deposited on said needle. The coating material of claim 5 is a non-noble metal including nickel or chromium. Nowhere in claim 5 is it required that the non-noble base metal include nickel or chromium, as stated by the Examiner. Accordingly, clarification and restatement of the Examiner's reasons for allowance is believed to be in order, and is hereby requested.

Claims 3 and 16 stand rejected as being anticipated by US 6,132,582 to King et al. For the following reasons, the Examiner's rejections are traversed.

Claim 3 is directed toward an instrument including a needle for collecting liquid samples. The needle has a non-noble base metal and has an outer surface coated with a material having a lower chemical activity than that of the base metal. The coating material includes polyetheretherketone (PEEK). Claim 16 depends from claim 3.

Simply put, the King patent does not disclose or suggest a needle as defined in claim 3. Notably, the King needle does not have non-noble base metal that has an outer surface coated with PEEK. The Examiner has not indicated any portion of the disclosure of King as teaching the use of PEEK as a coating material for the base metal.

Accordingly, it is respectfully submitted that claim 3, and claim 16 that depends therefrom, is patentable over the King reference. Notice to that effect is requested.

Claims 3 and 16 stand rejected as being unpatentable over the combination of US Patent Publication 2002/0168778 to Andrien Jr. (hereafter Andrien) in view of US 6,793,632 to Sohrab. The Examiner's rejection is traversed for the following reasons.

Andrien teaches a sample injection apparatus including a disposable or reusable needle. The material of the needle is not disclosed in Andrien, except for the embodiments of Figs. 8-10, in which the outer surface of the needle is covered with a conductive material. It is submitted that PEEK is generally believed to be an insulative material. Further, it is considered apparent that if the outer surface is covered with a conductive material, the base material of the Andrien needle must be insulative, or else it will be functionally inoperable for the intended purpose.

Sohrab teaches a percutaneous micro-needle for sample collection. The micro-needle includes a solid wire core 106 and outer plating 114. The outer plating is conductive. An electrochemical cell is disposed between the wire core and the outer plating 114. A first cylindrical electrode 108 is formed around the wire core 106 and a second electrode 112 is electroplated onto the outer plating 114. It is believed that the wire core 106 is insulative and conductive electrode 108 is formed completely around this insulative core 106. Although not discussed in Sohrab, it is believed that the outer plating 114 may also be formed over an insulative substrate, and that the second electrode 114 is then electroplated onto just a portion of the outer plating. In any event, in Sohrab it is the inner portions or substrates that are formed from an insulative material, such as PEEK. After careful review of the Sohrab patent, it is respectfully submitted that Sohrab does not teach or suggest a needle "containing a non-noble base metal", as required by claim 3. Further, it is considered apparent that Sohrab does not teach such a needle "having an outer surface coated with a coating material that has a chemical activity lower than a chemical activity of the base metal of said needle, wherein said coating material includes a synthetic resin coating including polyetheretherketone that is coated on

said needle". Rather, at best Sohrab teaches that a base or body of the needle is formed from an insulative material (perhaps PEEK), and that the outer coating is conductive, and that portions of the outer coating may be covered with an electrode.

Insofar as neither of the reference teach or suggest a needle "containing a non-noble base metal and having an outer surface coated with a coating material .... wherein said coating material includes a synthetic resin coating including polyetheretherketone", it is respectfully submitted that even if the references were combined as advocated by the Examiner, the present invention would not result.

Further, it is respectfully submitted that there is no motivation or suggestion in the art of record that would lead one skilled in the art to combine the references in the manner proposed by the Examiner. The Andrien patent is directed toward solving problems associated with flow injection analysis, and only discloses a needle in a superficial manner. Notably, Andrien never discusses the material that the needle is formed from, let alone that the needle has an outer coating formed from PEEK. Sohrab, on the other hand, is directed toward a device for collecting small fluid samples from a patient, and discloses the needle configuration and construction at length, albeit contrary to that of the present invention. As noted above, it is submitted that the use of PEEK material in Sohrab is limited to the inner layers, at best, and cannot be construed as teaching a needle having a non-noble base metal over which an outer coating of PEEK material is formed.

The Examiner states that one skilled in the art would be motivated to combine the needle of Sohrab with the apparatus of Andrien (i.e., coating the Andrien needle with PEEK material) so as to ensure the integrity of the needle during a sterilization/washing procedure. However, sterilization is not an issue in Andrien, as

Andrien merely washes the needle following use. Accordingly, one skilled in the art would not be motivated to include PEEK to attain an 'advantage' that is not useful in the Andrien device.

It is further noted that neither reference indicates that PEEK would be particularly effective at maintaining the integrity of the needle during sterilization or washing. Absent some suggestion or motivation *in the art of record or generally known to those skilled in the art*, the required motivation for the combination is lacking. In this regard it is noted that Sohrab does not disclose any particular advantage to the use of PEEK, but rather only generically teaches that micro-needle material be able to withstand sterilization cycles. As noted hereinbefore, sterilization in Andrien is not an issue, so Andrien merely washes the needle, and this washing process is not disclosed as being a problem for the generic needle used in Andrien.

Based at least upon the foregoing arguments, it is submitted that there is no motivation to combine the references in the manner proposed. It is submitted that the present application provides the only motivation for such a combination and, as such, the rejection is invalid for hindsight.

For at least the foregoing reasons claim 3, and claim 16 that depends therefrom, is considered to be allowable over the combination of Andrien and Sohrab. Reconsideration and withdrawal of the rejections based upon this combination of references is requested.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite

prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. NGB-12930.

Respectfully submitted,

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